4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0124 (formerly Docket No. FDA-1975-N-0012)]

Consumer Antiseptic Rub Final Rule; Finding of Ineligibility for Inclusion in Final Monograph Questions and Answers; Guidance for Industry; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Consumer Antiseptic Rub Final Rule Questions and Answers." We are issuing this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act to help small businesses understand and comply with the Consumer Antiseptic Rub Final Rule; Finding of Ineligibility for Inclusion in Final Monograph (Consumer Antiseptic Rub FR). In the Consumer Antiseptic Rub FR, FDA established that 28 active ingredients used in nonprescription (also known as over-the-counter (OTC)) consumer antiseptic products intended for use without water (consumer antiseptic rubs) are not eligible for evaluation under FDA's OTC Drug Review, which was used to evaluate the safety and effectiveness of OTC drug products marketed in the United States on or before May 1972. The Consumer Antiseptic Rub FR also established that three active ingredients used in consumer antiseptic rubs are eligible for evaluation under the OTC Drug Review and granted requests to temporarily defer further rulemaking on these three eligible ingredients to allow for the development and submission of new safety and effectiveness data.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-0124 for "Consumer Antiseptic Rub Final Rule Questions and Answers." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Anita Kumar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5445, Silver Spring, MD 20993-0002, 301-796-1032.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Consumer Antiseptic Rub Final Rule Questions and Answers." We are issuing this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28)[1] to help small businesses understand and comply with the Consumer Antiseptic Rub FR (84 FR 14847, April 12, 2019), which established that 28 active ingredients are not eligible for evaluation under FDA's OTC Drug Review for use in consumer antiseptic rubs. Drug products containing these ineligible active ingredients will require approval under a new drug application or abbreviated new drug application before they can be marketed. In this final action, FDA also established that three active ingredients used in consumer antiseptic rubs are eligible for evaluation under the OTC Drug Review and granted requests to temporarily defer further rulemaking on these three ingredients to allow interested parties to complete the studies necessary to fill the safety and effectiveness data gaps identified for these three ingredients.

[1] 5 U.S.C. 601 (note).

This guidance reviews the content and effect of the final action, including identifying which active ingredients were found eligible and which were found not eligible for evaluation under the OTC Drug Review for use in consumer antiseptic rubs. In addition, this guidance explains when and how manufacturers must comply with the final action.

This Level 2 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on how small businesses can better understand and comply with the Consumer Antiseptic Rub FR. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs or https://www.regulations.gov.

Dated: December 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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